REVISED
DRAFT

Centers for Medicare and Medicaid Services

HCPCS Public Meeting Agenda for
JUNE 14, 2005
DRUGS, RADIOPHARMACEUTICALS, BIOLOGICALS AND RADIOLOGIC IMAGING AGENTS
(DAY 1)

Please note that this agenda contains preliminary decisions and do not necessarily reflect what the final decisions will be. Preliminary decisions provide a basis for comment at public meetings. All coding changes, when finalized will be published by mid November on the CMS HCPCS website at www.cms.hhs.gov/medicare/hcpcs, and effective January 1, 2006 unless otherwise noted in the HCPCS Annual Update or on a Quarterly Update.

The agenda includes a summary of each HCPCS code application on the agenda. The information provided in each summary reflects claims made by the applicant and should not be construed as a statement of fact or an endorsement by the federal government.

Each meeting day will begin at 9 a.m. and is scheduled to end at 5 p.m., E.S.T. However, because it is impossible to anticipate whether all presentations will fill their allotted time period (e.g. 15 minutes for Primary Speakers; or 5 minutes for "5-Minute Speakers"), we cannot commit specific items to specific time

frames, and we can only estimate the amount of meeting time that will be needed. Meetings may end earlier than 5:00 p.m. Meeting participants should arrive early and plan on the meeting commencing promptly at 9:00 a.m., and speakers are asked to please arrive prepared and wait until it is their turn to speak.

Meeting Agenda Item #1
June 14, 2005
HCPCS Request #05.34

Background/Discussion:

David I. Bell of Grifols Biologicals, Inc. has submitted a request to establish a code for an immune globulin intravenous (human) liquid, pasteurized, Trade Name: Flebogamma 5%, used to replace immunoglobulins in patients who have congenital or hereditary lack or deficiency of IgG. According to the requester, Flebogamma 5% is a liquid pasteurized intravenous immunoglobulin solution obtained from the plasma of normal U.S. donors. According to the requester, Flebogamma 5% is the only sorbitol stabilized immunoglobulin product available in the marketplace. The requester claims that it is manufactured using a proprietary process utilizing a stabilizer and other components which give rise to a significantly different risk profiles, including incidence of renal failure, stroke and myocardial infarction, by virtue of using sorbitol as a stabilizing agent which has not been associated with renal damage due to hyper-osmotic overload, or stroke or M.I. due to increased blood viscosity. Flebogamma is administered intravenously and dosed by weight. Most patients receive monthly infusions, although some require infusions on a more frequent basis. The usual dose of Flebogamma 5% for replacement therapy in primary humoral immunodeficiency diseases is 300 to 600 mg/kg body weight administered every 3 to 4 weeks. Doses may be adjusted over time to achieve the desired trough IgG levels and clinical response. It is supplied in single dose vials containing 0.5, 2.5, 5 or 10 gram vials of IgG as a 5% liquid solution. The requester claims that existing codes J1563 and J1564 do not allow for accurate billing according to dose by weight and claims that Medicare reimbursement is less than the cost of the product.

CMS HCPCS Workgroup Preliminary Decision:

1) Establish 4 new "Q" codes effective 4/1/2005:

Q9941 Injection, immune globulin, intravenous, lyophilized, 1 G.
Q9942 Injection, immune globulin, intravenous, lyophilized, 10 mg.
Q9943 Injection, immune globulin, intravenous, non-lyophilized, 1 G.
Q9944 Injection, immune globulin, intravenous, non-lyophilized, 10 mg.

2) Change coverage indicator to "not valid for Medicare" for J1563 and J1564, effective 4/1/2005.

3) Discontinue codes J1563 and J1564, effective 12/31/2005.

4) Discontinue 4 "Q" codes effective 12/31/2005.

5) Establish 4 new "J" codes to replace "Q" codes, using identical language, effective 1/1/2006.

Meeting Agenda Item #2
June 14, 2005
HCPCS Request #05.56

Background/Discussion:
Terry Tenbrunsel of Bayer Healthcare LLC has submitted a request to establish a J code for Immune Globulin Intravenous [Human], 10% Caprylate/Chromatography Purified, Trade Name: Gamunex®. According to the requester, Gamunex is indicated as a replacement therapy for primary immunodeficiency states in which severe impairment of antibody forming capacity has been shown. It is indicated in idiopathic thrombocytopenic purpura to rapidly raise platelet counts to prevent bleeding or allow a patient with ITP to undergo surgery. It is administered by intravenous infusion only. It is recommended that it initially be infused at a rate of 0.01 mL/kg per minute for the first 30 minutes. If well-tolerated, the rate may be gradually increased to a maximum of 0.08 mL/kg per minute. It is supplied as a solution for intravenous administration.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish 4 new "Q" codes effective 4/1/2005:

Q9941 Injection, immune globulin, intravenous, lyophilized, 1 G.
Q9942 Injection, immune globulin, intravenous, lyophilized, 10 mg.
Q9943 Injection, immune globulin, intravenous, non-lyophilized, 1 G.
Q9944 Injection, immune globulin, intravenous, non-lyophilized, 10 mg.

2) Change coverage indicator to "not valid for Medicare" for J1563 and J1564, effective 4/1/2005.

3) Discontinue codes J1563 and J1564, effective 12/31/2005.

4) Discontinue 4 "Q" codes effective 12/31/2005.

5) Establish 4 new "J" codes to replace "Q" codes, using identical language, effective 1/1/2006.

Meeting Agenda Item #3
June 14, 2005
HCPCS Request #05.35

Background/Discussion:

Mark Reese of Ortho Biotech Products has submitted a request to establish a code for high molecular weight hyaluronan, Trade Name: ORTHOVISC. According to the requester, ORTHOVISC is a high molecular weight, ultra-pure natural hyaluronan dissolved in physiological saline drug that is supplied in a single use syringe and is intended for one time use only. ORTHOVISC is used in the treatment of pain due to osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and to simple analgesics (e.g. acetaminophen). The treatment course consists of three or four intra-anticular injections administered weekly. The requester claims that combined analysis of two large clinical studies demonstrate significantly larger proportion of ORTHOVISC-treated patients achieving a 40% or 50% improvement in WOMAC pain score (Western Ontario McMaster) compared to controls. Clinical safety and efficacy studies have demonstrated symptomatic relief for 27 weeks.

CMS HCPCS Workgroup Preliminary Decision: Revise code J7317 to read: "sodium hyaluronate, per 20 to 30 mg dose for intra-articular injection", effective 1/1/2006, in order to include Orthovisc in the code category with similar products. Until the code is revised, use C9220 for HOPPS and J3490 for physicians' offices.

There is currently insufficient evidence of a difference in clinical outcome based on molecular weight and no payer identified a national program operating need to differentiate similar products based on molecular weight.

Meeting Agenda Item #4
June 14, 2005
HCPCS Request #04.137

Background/Discussion:

Marsha Kantor, of Sanofi-Synthelabo, Inc., has submitted a request to establish a code for sodium hyaluronate, Trade Name: Hyalgan®. Hyalgan is a prescription injectable material that has both pharmacologic and bio-mechanical properties. It is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy, and to simple analgesics, e.g., acetominophen. Intra-articular administration of Hyalgan into arthritic knees lead to an increase in the viscoelasticity of the synovial fluid. Activation of endogenous hyaluronate production, decreased hyaluronate degradation, increased extracellular matrix production in cartilage, extended maintenance of chondrocyte viability, modulation of inflammatory responses, and coating of pain receptor thereby dampening their activation have also been reported. The standard dose is 20 mg. It is administered by intra-articular injection. A treatment cycle consists of five injections given at weekly intervals. It is supplied as a sterile, non-pyrogenic solution in 2mL vials or 2mL pre-filled syringes, both of which contain 20mg. of Hyalgan.

CMS HCPCS Workgroup Preliminary Decision: Continue to code Hyalgan at existing J7317. The dose descriptor of J7317 will be revised, effective 1/1/06 to read "SODIUM HYALURONATE, PER 20 TO 30 MG DOSE FOR INTRA-ARTICULAR INJECTION" in order to include similar products in this category.

There is currently insufficient evidence to differentiate among products in this code category based on molecular weight or a therapeutic distinction.

Meeting Agenda Item #5
June 14, 2005
HCPCS Request #04.138

Background/Discussion:

Bill Gittinger, of Smith & Nephew, Inc., has submitted a request to establish a code for 1% sodium hyaluronate (hyaluronan), Trade Name: Supartz®. Supartz is a solution made up of highly purified, sodium hyaluronate, which is a natural chemical found in the body and is in particularly high concentrations in joint tissues and in the fluid that fills the joints. It acts like a lubricant and shock absorber in synovial fluid of a healthy joint. Osteoarthritis reduces a person's synovial fluids ability to protect and lubricate the joint. Supartz joint fluid therapy (2.5ml) is administered by intra-articular injection once a week for a total of five injections. It is supplied as a sterile, non-pyrogenic solution in a 2.5 ml pre-filled syringe. Each 2.5ml pre-filled syringe of Supartz contains sodium hyaluronate 25.0mg, sodium chloride 21.25 mg, dibasic sodium phosphate dodecahydrate 1.343mg., sodium dihydrogen phosphate dihydrate 0.04mg, and water for injection q.s..

CMS HCPCS Workgroup Preliminary Decision: Continue to code Supartz at existing J7317. The dose descriptor of J7317 will be revised, effective 1/1/06 to read "SODIUM HYALURONATE, PER 20 TO 30 MG DOSE FOR INTRA-ARTICULAR INJECTION" in order to include similar products in this category.

There is currently insufficient evidence to differentiate among products in this code category based on molecular weight or a therapeutic distinction.

Meeting Agenda Item #6
June 14, 2005
HCPCS Request #05.51

Background/Discussion:

Tom Mitro of ISTA Pharmaceuticals has submitted a request to establish a code for Ovine Hyaluronidase, Trade Name: Vitrase®. According to the requester, Vitrase is derived from ovine testes from New Zealand, a non-bovine spongiform encephalopathy (BSE) source. As a spreading agent, it has found medical applications in ophthalmic anesthesia, subcutaneous urography, hypodermoclysis, and the treatment of certain malignancies. It is a spreading or diffusing substance, which modifies the permeability of connective tissue through the hydrolysis of hyaluronic acid. Hyaluronidase hydrolyzes hyaluronic acid by splitting the glucosaminidic bond between C1of the glucosamine moiety and C4 of glucuronic acid. This temporarily decreases the viscosity of the cellular cement and promotes diffusion of injected fluids or of localized transudates or exudates, thus facilitating their absorption. Dosages range from 55 IU in 50 µL to 200,000 IU. It is commonly injected, including subcutaneous, peribulbar, Sub Tenons, retrobulbar and intravitreal. For certain malignancies, intravenous use may be utilized. Vitrase is supplied in sterile 6200 units of lyophilized ovine hyaluronidase non-preserved in a single use 5ml vial, one 1 mL sterile polycarbonate syringe and one 5 µm sterile needle. It is also supplied as 200 USP units/mL of ovine hyaluronidase non-preserved in a single use 2mL glass vial.

CMS HCPCS Workgroup Preliminary Decision: To establish a new "J" code.

J???? Injection, hyaluronidase, preservative free, up to 100 usp units.

Meeting Agenda Item #7
June 14, 2005
HCPCS Request #05.52

Background/Discussion:

Nick Poulios, PhD of Elan Pharmaceuticals, Inc. has submitted a request to establish a code for Natalizumab, Trade Name: Tysabri®. Applicant requests the following code language: Jxxxx INJECTION, NATALIZUMAB FOR INTRAVENOUS INFUSION, 300MG, to differentiate Tysabri from other products. According to the requester, Tysabri, the only humanized monoclonal antibody approved for the treatment of multiple sclerosis (MS), inhibits adhesion molecules on the surface of immune cells. Adhesion molecules allow cells to bind to each other, and in the case of MS, allow activated lymphocytes to bind to endothelial cells, which is a key step in these cells' entering the central nervous system to cause immune damage to the brain. Research suggests that Tysabri works by preventing these immune cells from migrating from the blood stream into the brain where they otherwise might cause inflammation and potentially damage nerve fibers and their insulation. Tysabri is a biologic administered by intravenous infusion over a period of approximately one hour and is indicated for the treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations. The recommended dose is 300 mg IV infusion every four weeks. It is supplied as a sterile, colorless, and clear to slightly opalescent concentrate for IV infusion. Each package contains 300mg of Tysabri in a single-use vial.

CMS HCPCS Workgroup Preliminary Decision: Establish a new "J" code.

J???? Injection, natalizumab, 1 mg.

Meeting Agenda Item #8
June 14, 2005
HCPCS Request #05.153

Background/Discussion:

Lisa Colleran of LifeCell Corporation submitted a request to establish a series of 6 codes to distinguish varying thicknesses of Decellularized human tissue; human allogeneic skin; acellular tissue; allograft, Trade Name: AlloDerm® Regenerative Tissue Matrix. The applicant suggests the following language for the requested 6 codes: "Dermal tissue of human origin with or without other bioengineered or processed elements, without metabolically active elements, *by thickness*, per square centimeter". The requester claims that a series of codes is needed to account for different procedures, (implant and/or graft); thickness, and price). According to the requester, AlloDerm® is a regenerative tissue matrix. AlloDerm® acellular dermal graft is a human donor-derived single layer decellularized dermal sheet product for the repair or replacement of human tissue that is freeze dried before packaging. AlloDerm® is used in various procedures for the replacement or repair of damaged or inadequate integumental tissue including closing complicated ventral/incisional hernias, breast reconstruction, and open wound repairs. The tissue derived component is comprised of native human dermal architecture, consisting of about 70-85% collagen (mainly type 1 w/additional collagen type III and IV components), less than 2% each of the chondroitin sulfate and hyaluronic acid glycosaminoglycans, and up to 10% elastin.

CMS HCPCS Workgroup Preliminary Decision: No new code.

This implantable product is not separately payable in any setting. In the inpatient setting, this item is included in the DRG. In an outpatient setting the product is included in the APC or in the practice expense. For Medicare, it is inappropriate to bill using C9221, J7344, or any miscellaneous code to identify this product.

Meeting Agenda Item #9
June 14, 2005
HCPCS Request #05.152

Background/Discussion:
Sajini Thomas of Wright Medical Technology, Inc. submitted as request to establish a code for Micronized Acellular Soft-Tissue Scaffold, Trade Name: GRAFTJACKET® XPRESS Flowable Soft-Tissue Scaffold. According to the requester, this product is a micronized (finely ground) decellularized soft tissue scaffold indicated for the repair or replacement of damaged or inadequate integumental tissue, specifically deep, dermal wounds that exhibit tunneling, and extension from the wound base that may extend deep into the tendon and bone. It is processed and regulated in accordance with the FDA's requirements for the procurement and processing of banked human tissues (CFR Title 21, Part 1270 and 1271) and standards and guidelines of the AATB. The GRAFTJACKET® XPRESS is a soft tissue graft (reconstituted as a "gel"), which is comprised solely of human dermal tissue, including its native protein and collagen structure and essential biochemical composition. The re-hydrated skin substitute scaffold is placed into the tunnels or tracts and produces the same or superior clinical outcomes with a minimally invasive procedure. The applicant claims that C9222 DECELLULARIZED SOFT TISSUE SCAFFOLD, PER 1 CC was established by CMS in 2005 for use in HOPPS, and that the sheet form of the product was assigned to J7344 DERMAL TISSUE, OF HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER in 2005. The applicant requests a J code for use in the physician office and ASC settings to identify the syringe-delivered form of this product. The applicant suggests the following language for the requested code: "Acellular soft-tissue scaffold gel, per 1 cc". The product is supplied in powder form as part of a kit that includes: 2cc volume of GRAFTJACKET® EXPRESS powder packaged 5cc syringe; 3cc syringe for rehydration; 21 G needle, 19G OPTIVA® catheter; and syringe connector.

CMS HCPCS Workgroup Preliminary Decision: No new code.

Your reported sales volume was insufficient to support your request for a revision to the national codes. There must be sufficient claims activity or volume, as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code. In addition, more clinical evidence is needed to demonstrate that this product provides a better clinical outcome compared to similar products. Only one study with 15 patients was completed at the time of application.

Appropriate code assignment is made by the insurer in whose jurisdiction the claim is filed. For Medicare, use A4649 (surgical supply; miscellaneous), for a physician's office. In an ASC, the cost of this product is bundled into the facility fee. For coding guidance for private sector health insurance systems, please contact the individual private

insurance contractor. For Medicaid systems, please contact the Medicaid Agency in the state in which the claim is being filed. No insurer identified a national program operating need to alter the existing code set to describe this item.

Meeting Agenda Item #10
June 14, 2005
HCPCS Request #05.154

Background/Discussion:

Kathleen Schaum of Kathleen Schaum & Associates, Inc. submitted a request to establish a code for acellular porcine-derived, small intestine submucosa products, trade names: OASIS® Wound Matrix and OASIS® Burn Matrix. The applicant requests a new J-code, to differentiate acellular, procine-derived, small intestine submucosa products from already existing J-codes assigned to dermal and epidermal tissues of human and non-human origin. Oasis is biologically derived, extracellular matrix-based wound care products, translucent and off-white in color. They are obtained from the small intestinal submucosa (SIS) layer of the domestic pig. The isolated submucosa is chemically cleaned, decellularized, freeze-dried, and terminally sterilized. According to the applicant, existing codes (J7340-J7344) do not accurately describe this product for the following reasons: 1) this product is acellular and is not dermal or epidermal; 2) this product is of non-human origin; 3) this product contains bioactive components, however, according to the applicant, "it is not with/without metabolically active elements". The applicant suggests the following language for the requested code: "Acellular submucosal tissue of non-human origin (e.g. porcine), with bioactive components, per square centimeter".

CMS HCPCS Workgroup Preliminary Decision: To establish a new "J" code.

J???? Dermal (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter.

Meeting Agenda Item #11
June 14, 2005
HCPCS Request #05.42
(Duplicate of Request #04.152)

Background/Discussion:

Barbara Ossias, of GE Healthcare, has submitted request establish separate codes for Technetium-99m Exametazime, (Ceretec™) for use in cerebral scintography and infection imaging. According to the requester, Ceretec can be used as an adjunct in the detection of altered regional cerebral perfusion in stroke. Without methylene blue stabilization, it is indicated for leukocyte labeled scintigraphy as an adjunct in the localization of intra-abdominal infection and inflammatory bowel disease. Currently, A9521 (Supply of radiopharmaceutical diagnostic imaging agent, technetium Tc 99m exametazine, per dose) is used to denote Ceretec for both infection imaging and brain imaging, despite the variants in how the product is administered for each utilization. The Ceretec kit is supplied as a kit containing five vials with different clinical utilizations. Each vial of Ceretec contains a predispensed sterile, non-pyrogenic, lyophilized mixture of 0.5mg Exametazime. In addition, each package contains five 1ml vials of Methylene Blue Injection USP and five 4.5ml vials of 0.003 M Monobasic Sodium Phosphate USP and Dibasic Sodium Phosphate USP in 0.9% Sodium Chloride Injection USP.

CMS HCPCS Workgroup Preliminary Decision:

1) Revise code A9521 to read: (technetium TC-99M exametazine, per study dose, up to 25 millicuries).

2) Use revised code A9521 for leukocyte labeled scintography.

3) Establish a new "A" code.
A???? Injection, methylene blue, 1ML

Meeting Agenda Item #12
June 14, 2005
HCPCS Request #05.31

Background/Discussion:
Mike Brown of Biogen Idec, Inc. has submitted a request to modify HCPCS code A9523 (Supply of radiopharmaceutical therapeutic imaging agent, Yttrium 90 Ibritumomab Tiuxetan, per mCi) to read "per dose" rather than "per mCi". According to the requester, Zevalin is indicated for the treatment of patients with relapsed or refractory low-grade, follicular or CD20+ transformed B-cell non-Hodgkins lymphoma, and for the treatment of patients with RITUXAN-refractory follicular non-Hodgkins lymphoma. It is prepared by a radiopharmacist in a patient-specific single use dose, who then sends the final product to the licensed provider facility in a pre-filled syringe for patient administration.

CMS HCPCS Workgroup Preliminary Decision:
1)Discontinue code A9523 "supply of radiopharmaceutical therapeutic imaging agent, yttrium 90 ibritumomab tiuxetan, per mCi.

2) Establish a new "A" code.
A???? Yttrium Y-90 ibritumomab tiuxetan, therapeutic agent, per study dose, up to 40 millicuries.

Meeting Agenda Item #13
June 14, 2005
HCPCS Request #05.32
(Duplicate of Request #04.151)

Background/Discussion:

Mike Brown of Biogen Idec, Inc. has submitted a request to modify HCPCS code A9522 (Supply of radiopharmaceutical diagnostic imaging agent, Indium-111 Ibritumomab Tiuxetan, per mCi) to read "per dose" rather than "per mCi". According to the requester, Zevalin is indicated for the treatment of patients with relapsed or refractory low-grade, follicular or CD20+ transformed B-cell non-Hodgkins lymphoma, and for the treatment of patients with RITUXAN-refractory follicular non-Hodgkin's lymphoma. ^{111}Indium Zevalin is prepared using the ^{111}Indium Zevalin kit, which contains all of the non-radioactive ingredients necessary to produce a single dose of ^{111}Indium Zevalin. The radiopharmacist prepares a single patient-specific dose, and then sends the final product to the licensed provider facility in a pre-filled syringe for patient administration.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code A9522 supply of radiopharmaceutical diagnostic imaging agent, indium-111 ibritumomab tiuxetan, per MCI.

2) Establish a new "A" code.
A???? Indium-111 ibritumomab tiuxetan, diagnostic agent, per study dose, up to 5 millicuries.

Meeting Agenda Item #14
June 14, 2005
HCPCS Request #05.37

Background/Discussion:

Marie DiFiore of Bracco Diagnostics has submitted a request to change existing code Q3000 " SUPPLY OF RADIOPHARMACEUTICAL DIAGNOSTIC IMAGING AGENT, RUBIDIUM RB-82, PER DOSE" to an "A" code for Rubidium Chloride Rb-82, Trade Name: CardioGen-82®. Proposed code A95XX with exact same language as Q3000. According to the requester, CardioGen-82 is a generator containing accelerator produced strontium Sr-82 absorbed on stannic oxide in a lead-shielded column and provides a means for obtaining sterile nonpyrogenic solutions of rubidium chloride Rb-82 injection. The injection is a myocardial perfusion agent that is useful in distinguishing normal from abnormal myocardium in patients with suspected myocardial infarction. CardioGen-82 (Rubidium Rb 82 Generator) must be used with an infusion system specifically labeled for use with the generator and capable of accurate measurement and delivery of doses of rubidium chloride Rb 82 injection not to exceed a single dose of 2220 MBq (60 mCi) and a cumulative dose of 4440 MBq (120 mCi).

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code Q3000 effective 12/31/2005.

2) Establish a new "A" code, effective 1/1/2006.
A???? Rubidium RB-82, per study dose, up to 60 millicuries.

Meeting Agenda Item #15
June 14, 2005
HCPCS Request #05.185

Background/Discussion:
Skip E. Purich of ChiPhoClin, Inc. submitted a request to establish a code for human secretin, trade name: ChiRhoStim. According to the requestor, ChiRhoStim (synthetic human secretin) is an exact copy of a naturally occurring human hormone produced by cells in the intestinal tract. Secretin is used as a diagnostic agent. It naturally stimulates the exocrine pancreas gland and tests to see whether the pancreas is functioning normally or not in terms of measuring the amount and content of pancreatic juice produced after administration of secretin. Secretin stimulates gastrin secretion to aid in the diagnosis of gastrinoma. It also stimulates pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP).

CMS HCPCS Workgroup Preliminary Decision: No new code.

In a hospital in-patient environment, this product is included in the DRG. In a physician's office, it is included in the CPT (in the practice expense for the ERCP procedure). In an ASC, it is included in the payment. No insurer identified a national program operating need to separately identify this product because it is bundled, and not separately payable.

Meeting Agenda Item #16
June 14, 2005
HCPCS Request #05.33

Background/Discussion:

Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to convert C1093 SUPPLY OF RADIOPHARMACEUTICAL DIAGNOSTIC IMAGING AGENT, TECHNETIUM TC 99M FANOLESOMAB, PER DOSE (10 - 20 mCi) to an A or J code. The language suggested by the requester is AXXXX Supply of Radiopharmaceutical diagnostic imaging agent, Technetium Tc99m fanolesomab per dose (10-20 mCi). The product that is the subject of this request, NeutroSpec™, according to the requester, is a Technetium labeled antibody that is injected directly into a patient. It is an intravenously administered diagnostic imaging agent that binds in vivo, with high affinity and specificity to white blood cells and myeloid precursors. It is administered in a single intravenous dose of 10-20 mCi for diagnostic nuclear imaging procedures.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code C1093 .

2) Establish a new "A"code.

A???? Technetium TC-99M fanolesomab, per study dose, up to 25 millicuries.

Meeting Agenda Item #17
June 14, 2005
HCPCS Request #05.28A-E

Background/Discussion:

Request #05.28A-E

Lisa Saake, of Tyco Healthcare/Mallinckrodt, has submitted a request modify the coding for low osmolar contrast drugs for 2006. She has presented two options, which are as follows:

Option 1: Revise A4644 to include a quantity of contrast administered. For example, A4644 Low osmolar contrast 100-199 concentration, per mL. Delete A4645 and replace it with a series of codes that more accurately describes the products on the market today. For example, AXXXX Low osmolar contrast 240 concentration, per mL. Delete A4646 and replace it with a series of codes that more accurately describes the products on the market today. For example, AXXXX Low osmolar contrast 300 concentration, per mL.

Option 2: Delete codes A4644-A4646 and create new codes for low osmolar agents based on each manufacturer's chemical ingredient and concentration of iodine, as below:

Optiray 160– Indicated for intra-arterial digital subtraction angiography. Ioversol injection 34% (Optiray 160) is available in 50 ml and 100 ml glass bottles. It opacifies vessels in the path of the flow of the contrast medium permitting radiographic visualization of the internal structures for diagnostic or therapeutic purposes.

Optiray 240 – Indicated for angiography and venography as well as contrast enhanced computed tomographic imaging of the head and body. It is also indicated for intravenous excretory urography. Ioversol 51% (Optiray 240) is available in 50 mL, 100 mL, 150 mL, and 250 mL glass bottles, 50 mL hand-held syringes, and 125 mL power injector syringes.

Optiray 300 - Indicated for cerebral angiography and peripheral arteriography, as well as contrast enhanced computer tomographic imaging of the head and the body, venography and intravenous excretory urography. Ioversal Injection 64% (Optiray 300) is supplied in 50 mL, 100 mL, 150 mL, and 200 mL glass bottles, 50 mL hand held syringes, 100 mL power injector syringe, and 500 mL Pharmacy bulk pack.

Optiray 320 - Indicated in adults for angiography throughout the cardiovascular system. It enhances computed tomographic imaging through augmentation of radiographic efficiency for diagnostic purposes or therapeutic patient management. Ioversal Injection 68% is supplied in 20 mL, 30 mL, 50 mL, 75 mL, 100 mL, 200 mL glass bottles, 30 mL and 50 mL hand held syringes, 50 mL, 75 mL, 100 mL and 125 mL power injector syringes, and 250 mL pharmacy bulk packs.

Optiray 350– Indicated in adults for peripheral and coronary arteriography and left ventriculography. It is also indicated for contrast enhanced computer tomographic imaging of the head and the body, intravenous excretory urography, intravenous digital

subtraction angiography and venography. It is indicated in children for angiocardiography. Ioversol Injection 74% (Optiray 350) is available in 50 mL, 75 mL, 100 mL, 150 mL, and 200 mL glass bottles, 30 mL and 50 mL hand held syringes, 50 mL, 75 mL, 100 mL, and 125 mL power injector syringes, and 250 mL and 500 mL pharmacy bulk packs.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish seven new “Q” codes effective 4/1/2005.

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646 effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/2005, no crosswalk.

Meeting Agenda Item #18
June 14, 2005
HCPCS Request #05.30

Background/Discussion:
Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to discontinue A4643 and A4647 and establish new codes that more accurately describe magnetic resonance contrast agents based on the chemical ingredient. In addition, the requestor would like to add a quantity description, per mL, to the code. Specifically, the requester suggests the establishment of a new code and recommended the following language: "GADOVERSETAMIDE INJECTION, PER ML", Trade Name: OptiMARK®. According to the requester, OptiMARK® is a paramagnetic agent that develops in a magnetic moment when placed in a magnetic field. The relatively large magnetic moment can enhance the relaxation rates of water protons in its vicinity leading to an increase in signal intensity, (brightness) of tissue. OptiMARK® is available in 5, 10, 15 and 20mL glass vials and 10, 15, 20, and 30mL plastic syringes.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 3 "Q" codes, effective 4/1/2005.

Q9952 Injection, gadolinium-based magnetic resonance contrast agent, per ml.
Q9953 Injection, iron-based magnetic resonance contrast agent, per ml.
Q9954 Oral magnetic resonance contrast agent, per 100 ml.

2) Discontinue codes Q9952-Q9954 effective 12/31/2005 and crosswalk to new "A" codes.

3) Change coverage indicator to "not valid for Medicare" for codes A4643 & A4647, effective 3/31/2005.

4) Establish 3 new "A" codes identical to the discontinued "Q" codes, effective 1/1/2006.

5) Discontinue codes A4643 and A4647 effective 12/31/2005, no crosswalk.

Meeting Agenda Item #19
June 14, 2005
HCPCS Request #05.29

Background/Discussion:
Lisa Saake of Tyco Healthcare/Mallinckrodt has submitted a request to:
Option 1: Revise code A4644 to include a quantity of contrast administered, delete A4645 and A4646 and replace them with a series of codes that more accurately describe the products on the market today, or
Option 2: Delete codes A4644-A4646 and create new codes for low osmolar agents based on each manufacturer's chemical ingredient and concentration of iodine.
This request would also include the establishment of a code for Ioxaglate Meglumine 39.3% and Ioxaglate Sodium 19.6% Injection USP, Trade Name: Hexabrix.

According to the requester, Hexabrix opacifies vessels in the path of the flow of contrast medium permitting readiographic visualization of the internal structures for diagnostic or therapeutic purposes. It enhances computed tomographic imaging through augmentation of radiographic efficiency for diagnostic purposes or therapeutic patient management.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes, effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/05, no crosswalk.

Meeting Agenda Item #20
June 14, 2005
HCPCS Request #05.43

Background/Discussion:
Tamar Thompson, of Amersham Health Inc., d.b.a. GE Healthcare, has submitted a request to establish a unique code for iso-osmolar contrast materials, including Visipaque, and other future IOCM products. According to the requester, Visipaque is a dimeric, nonionic, water soluble, iodinated, radiographic contrast medium that is isosmolar to blood at all clinically relevant concentrations. It is administered via intravascular administration and delivers twice the iodine of other contrast agents per molecule with less than half of the osmality of conventional low osmolar agents, and significantly less than high osmolar agents providing advantages, according to recent literature, for high risk patients. It is used to visualize organs. Contrast mediums work by blocking x-rays, thus increasing the visual contrast of soft tissues in the body.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes, effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/05, no crosswalk.

There is currently insufficient evidence to differentiate between iso-osmolar and low osmolar contrast agents based on clinical outcome.

Meeting Agenda Item #21
June 14, 2005
HCPCS Request #05.49

Background/Discussion:
Jay Schafer of Berlex Laboratories submitted a request to establish a code for gadopentetate dimeglumine, trade name: Magnevist®. According to the requester, Gadopentetate dimeglumine is a paramagnetic extracellular contrast drug for Magnetic Resonance Imaging (MRI). Gadopentetate dimeglumine is used to detect and characterize lesions with abnormal vascularity. Gadopentetate dimeglumine gives radiologists the ability to distinguish normal and abnormal tissues in MR exams. This impacts the confidence and accuracy of the diagnosis as well as the speed of the MRI exam. Gadopentetate dimeglumine is injected either directly into a vein or through a catheter into an artery prior to magnetic imaging procedure. The recommended dosage of gadopentetate dimeglumine is 0.2 ml/kg (0.1 mmol/kg) administered intravenously at a rate not to exceed 10mL per 15 seconds.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 3 "Q" codes, effective 4/1/2005:

Q9952 Injection, gadolinium-based magnetic resonance contrast agent, per ml.
Q9953 Injection, iron-based magnetic resonance contrast agent, per ml.
Q9954 Oral magnetic resonance contrast agent, per 100 ml.

2) Discontinue codes Q9952-Q9954 effective 12/31/2005 and crosswalk to new "A" codes.

3) Change coverage indicator to "not valid for Medicare" for codes A4643 & A4647 effective 3/31/2005.

4) Establish 3 new "A" codes identical to the discontinued "Q" codes effective 1/1/2006.

5) Discontinue codes A4643 and A4647 effective 12/31/05, no crosswalk.

Meeting Agenda Item #22
June 14, 2005
HCPCS Request #05.45

Background/Discussion:

Jay Schafer of Berlex Laboratories submitted a request to establish a unique code for Iopromide, Trade Name: Ultravist®. According to the requester, Ultravist® (Iopromide) is a nonionic, water soluble, tri-iodinated x-ray contrast agent for intravascular administration. Intravascular injection of iopromide opacifies those vessels in the path of flow of the contrast agent, permitting radiographic visualization of the internal structures until hemodilution occurs. Ultravist® (Iopromide) is injected either directly into a vein or through a catheter into an artery prior to x-ray imaging procedure. Injection for any patient scheduled to undergo an imaging procedure that requires the use of a contrast agent (CAT scan, IVP, arteriogram, angiogram, cardiac cath procedure, etc). According to the applicant, existing codes A4644, A4645 and A4646 describing low osmolar contrast agents "do not effectively distinguish drugs which are separate chemical entities".

CMS HCPCS Workgroup Preliminary Decision:

1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/2005, no crosswalk.

Meeting Agenda Item #23
June 14, 2005
HCPCS Request #05.50

Background/Discussion:
John Warner of Guerbet LLC has submitted a request to establish 2 codes for Oxilan (Ioxilan) Injection: one for 300mgI/ml; and one for 350 mgI/ml. According to the requester, Oxilan Injection is a non-toxic, iodinated, low osmolality contrast medium used for contrast enhancement during x-ray and CT examination procedures. It provides contrast needed to adequately image vasculature, internal organs, etc. due to atoms of iodine carried by the molecule, which are optically dense, thereby giving an image with different visual gradations. It is supplied as Oxilan 300mg/mL and Oxilan 350 mg/mL.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish the following 7 "Q" codes Q9945-Q9951 effective 4/1/2005:

Q9945 Low osmolar contrast material, up to 149 mg/ml iodine concentration, per ml.
Q9946 Low osmolar contrast material, 150-199 mg/ml iodine concentration, per ml.
Q9947 Low osmolar contrast material, 200-249 mg/ml iodine concentration, per ml.
Q9948 Low osmolar contrast material, 250-299 mg/ml iodine concentration, per ml.
Q9949 Low osmolar contrast material, 300-349 mg/ml iodine concentration, per ml.
Q9950 Low osmolar contrast material, 350-399 mg/ml iodine concentration, per ml.
Q9951 Low osmolar contrast material, 400 or greater mg/ml iodine concentration, per ml.

2) Change coverage indicator to "not valid for Medicare" for codes A4644-A4646, effective 3/31/2005.

3) Discontinue 7 "Q" codes Q9945-Q9951 effective 12/31/2005 and crosswalk to corresponding new "A" codes.

4) Establish 7 "A" codes effective 1/1/2006 that read exactly as Q9945-Q9951.

5) Discontinue codes A4644, A4645 and A4646 on 12/31/2005, no crosswalk.

Meeting Agenda Item #24
June 14, 2005
HCPCS Request #05.54

Background/Discussion:
Kathy Francisco of The Pinnacle Health Group, Inc. has submitted a request to establish a code Perflexane Lipid Microspheres, Trade Name: Imagent®. According to the requester, Imagent is a kit for the preparation of perflexane lipid microspheres for injectable suspension. It is a sterile, non-pyrogenic white powder with a diluted perflexane headspace that, after reconstitution into a suspension of microspheres is used for contrast enhancement during the indicated ultrasound imaging procedures. It is indicated for use in subjects with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. Imagent must be reconstituted and withdrawn from the vial via the supplied vented 5µm filter dispensing pen. The recommended dose is 0.00625 mL/kg (0.125 mg/kg) administered as a single intravenous bolus over a period of not less then 10 seconds and immediately followed by a saline flush. Imagent must be used within 60 minutes of reconstitution. Imagent kit for the preparation of Perflexane-Lipid Microspheres Injectable Suspension is supplied for single-use and each kit contains a 10-mL glass vial containing 200mg of Imagent powder, a 20-mL plastic vial of Sterile Water for Injection, and 10-mL disposable plastic sterile syringe, a sterile, vented 5µm filter dispensing pen, and a package insert.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish three "Q" codes as follows, effective 4/1/2005.

Q9955 Injection, perflaxane lipid microspheres, per ml.
Q9956 Injection octafluoropropane, per ml.
Q9957 Injection, perflutren lipid microspheres, per ml.

2) Discontinue Q9955-57 effective 12/31/2005 and crosswalk to three new “A” codes.

3) Establish three new “A” codes identical to discontinued Q9955-57, effective 1/1/2006.

Meeting Agenda Item #25
June 14, 2005
HCPCS Request #05.115

Background/Discussion:
Tuana Pryor of Bristol-Myers Squibb Medical Imaging has submitted a request to establish a code for perflutren lipid microsphere injectable suspension, Trade Name: Definity® and recommends the following language: INJECTION, ACTIVATED PERFLUTREN LIPID MICROSPHERE, PER 2ML. According to the requestor, Definity is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border. The visualization of cardiac structures is necessary for a complete assessment of the echocardiographic image. It is administered intravenously, with a typical dose being 1.3 mL. It is supplied sterile as a single use 2-mL clear glass vial.

CMS HCPCS Workgroup Preliminary Decision:
1) Establish a new "Q" code, effective 4/1/2005.
Q9957 Injection, perflutren lipid microspheres, per ml.

2) Discontinue code C9112, effective 12/31/2005.

3) Discontinue code Q9957, effective 12/31/2005.

4) Establish a new "A" code to replace Q9957, effective 1/1/2006.

Meeting Agenda Item #26
June 14, 2005
HCPCS Request #04.153

Background/Discussion:
Lisa Saake of Healthcare Economics submitted a request to discontinue code Q3010 and establish a "J" code for technetium Tc99m labeled red blood cells, trade name: UltraTag® RBC. UltraTag is a radiopharmaceutical used for blood pool imaging, including cardiac first pass and gated equilibrium imaging; and for detection of sites of gastrointestinal bleeding. Ultra tag causes technetium Tc99m tracer to stick to red blood cells allowing the nuclear imaging camera to follow the flow of blood. The recommended dosage of ultra tag is 10–20 mCi. It is supplied in two components; a non-radioactive component containing the reaction vials and a 20-30mCi of Technetium Tc99m.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3010, effective 12/31/05

2) Establish new code A????, "TECHNETIUM TC-99M LABELED RED BLOOD CELLS, PER STUDY DOSE, UP TO 45 MILLICURIE", effective 1/1/06

Meeting Agenda Item #27
June 14, 2005
HCPCS Request #04.154

Background/Discussion:
Lisa Saake of Health Care Economics submitted a request to discontinue code Q3009 and establish a "J" code for Technetium Tc99m oxidronate, trade name: TechneScan HDP®. TechneScan is a diagnostic skeletal imaging agent used to demonstrate areas of altered osteogenesis in adult and pediatric patients. It is injected intravenously and is distributed via blood flow throughout the body. TechneScan passively diffuses into the extravascular and extracellular spaces and binds to the hydration shell around the bone crystal. Delayed images will demonstrate the radionuclide bound to the bone crystal, depicting the skeletal system. Recommended dosage of TechneScan is 10-20mCi. It is supplied as a lyophilized powder, packaged under nitrogen in vials for intravenous administration.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue code Q3009, effective 12/31/05

2) Establish new code A???? "TECHNETIUM TC-99M OXIDRONATE, PER STUDY DOSE, UP TO 45 MILLICURIES", effective 1/1/06

Meeting Agenda Item #28
June 14, 2005
HCPCS Request #04.155

Background/Discussion:

Lisa Saake, Director of Health Care Economics, submitted a request to discontinue code Q3005 and establish a "J" code for technetium Tc99m mertiatide, trade name: TechneScan Mag3®. TechneScan is a renal imaging agent used to treat congenital and acquired abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatrics patients. Following intravenous injection of technetium Tc99m Mertiatide, the appearance, concentration, and excretion of the tracer in the kidney can be monitored to assess renal function. The suggested dosage for renal function and imaging studies is 5-10 mCi. Technescan is supplied as a sterilized, nonpyrogenic lyophilized powder. Each vial contains betiatide. The vial is reconstituted in a nuclear pharmacy with sterile Sodium Pertechnetate Tc99m forming Technetium mertiatide.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code Q3005, effective 12/31/05

2) Establish new A???? "TECHNETIUM TC-99M MERTIATIDE, PER STUDY DOSE, UP TO 25 MILLICURIES", effective 1/1/06

Meeting Agenda Item #29
June 14, 2005
HCPCS Request #04.156

Background/Discussion:

Lisa Saake of Health Care Economics submitted a request to discontinue code Q3007 and establish a "J" code for sodium phosphate solution, trade name: Sodium Phosphate P-32 Solution. Sodium Phoshate is a radiopharmaceutical used to treat polycythemia vera. It is also effective for the treatment of chronic myelocytic leukemia and chronic lymphocytic leukemia. Polycythemia vera is a disorder that stimulates overproduction of red blood cells, white blood cells, and platelets. Sodium phosphate travels to the bone marrow and impacts the overactive marrow cells. Recommended dosage is 1-8 millicurie depending on the stage of disease and the size of patient. Sodium Phosphate is supplied as a sterile, nonpyrogenic solution in single dose vials containing 5 mCi of phosphorus P-32.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code Q3007, effective 12/1/05

2) Establish new code A???? "SODIUM PHOSPHATE P-32, PER MILLICURIE", effective 1/1/06

Meeting Agenda Item #30
June 14, 2005
HCPCS Request #04.157

Background/Discussion:

Lisa Saake of Health Care Economics submitted a request to discontinue code Q3011 and establish a "J" code for chromic phosphate P 32 suspension, trade name: Phosphocol® P-32. Phosphocol is a radiopharmaceutical employed by intracavitary instillation for the treatment of peritoneal or pleural effusions caused by metastatic disease and may be injected interstitially for the treatment of cancer. Phosphocol treatment results in cessation or significant decrease in ascites and pleural effusion caused by ovarian, renal, breast and lung cancers or GI tract tumors. Recommended dosage is 10-20mCi. Phosphocol is supplied as a sterile, nonpyrogenic aqueous suspension in a 15 mCi single dose vial.

CMS HCPCS Workgroup Preliminary Decision:

1) Discontinue code Q3011, effective 12/31/2005

2) Establish new code A????, CHROMIC PHOSPHATE P-32 SUSPENSION, PER MILLICURIE, effective 1/1/06

Meeting Agenda Item #31
June 14, 2005
HCPCS Request #04.158

Background/Discussion:
Lisa Saake of Health Care Economics submitted a request to discontinue code Q3008 and establish a "J" code for Indium-In-111 Pentetreotide, trade name: OctreoScan. OctreoScan is a radiopharmaceutical agent used for the scintigraphic localization of primary and metastic neuroendocrine tumors bearing somatostatin receptors. Indium III works by binding to somatostatin receptors. Recommended dosage of OctreoScan is 6.0 mCi given through intravenous administration. It is supplied as a kit containing an OctreoScan reaction vial, and a vial containing Indium In-111 chloride sterile solution.

CMS HCPCS Workgroup Preliminary Decision:
1) Discontinue Q3008, effective 12/31/2005

2) Establish new code A????, "INDIUM IN-111 PENTETREOTIDE, PER MILLICURIE", effective 1/1/06

Meeting Agenda Item #32
June 14, 2005
HCPCS Request #04.159

Background/Discussion:
Denise Merlino of the Society of Nuclear Medicine submitted a request to modify the descriptions of 57 codes for radiopharmaceuticals. These changes are being requested so that the radiopharmaceuticals codes can be consistent in abbreviations and terms used in both short and long descriptors; and to accurately reflect the quantity or unit that is typically purchased, supplied, and administered to the patient. The first recommendation is that the words "supply of" and "imaging" can be removed primarily because these words do not provide any additional clarification to product being described. Secondly, some of the units of measurement should read "per dose". Thirdly, it is requested that all "C" and "Q" codes for radiopharmaceuticals be converted to "A" codes. It is also recommended that radiopharmaceuticals be assigned a consistent designation in column listed by CMS as PI1 for all radiopharmaceuticals under the drug section.

CMS HCPCS Preliminary Decision:
1) Revise code A4641 to read: "RADIOPHARMACEUTICAL DIAGNOSTIC AGENT, NOT OTHERWISE CLASSIFIED"

2) Revise code A4642 to read: "INDIUM IN-111 SATUMOMAB PENDETIDE, PER STUDY DOSE, UP TO 6 MILLICURIES"

3) Revise code A9500 to read: "TECHNETIUM TC-99M SETAMIBI, PER STUDY DOSE, UP TO 45 MILLICURIES"

4) Revise code A9502 to read: "TECHNETIUM TC-99M TETROFOSMIN, PER STUDY DOSE, UP TO 45 MILLICURIES"

5) Revise code A9503 to read: "TECHNETIUM TC-99M MEDRONATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

6) Revise code A9504 to read: "TECHNETIUM TC-99M APCITIDE, PER STUDY DOSE, UP TO 25 MILLICURIES"

7) Revise code A9505 to read: "THALLIUM TI-201 THALLOUS CHLORIDE, PER MILLICURIE"

8) Revise code A9507 to read: "INDIUM IN-111 CAPROMAB PENDETIDE, PER STUDY DOSE, UP TO 25 MILLICURIES"

9) Revise code A9508 to read: "IODINE I-131 IOBENGUANE SULFATE, DIAGNOSTIC AGENT, PER 0.5 MILLICURIE"

10) Revise code A9510 to read: "TECHNETIUM TC-99M DISOFENIN, PER STUDY DOSE, UP TO 25 MILLICURIES"

11) Discontinue codes A9511, A9513, A9514, A9515, A9519, A9520, A9522, A9523, A9533, A9534, eff. 12/31/2005

12) Establish new code A????, "TECHNETIUM TC-99M DEPREOTIDE, PER STUDY DOSE, UP TO 45 MILLICURIES"

13) Revise code A9512 to read: "TECHNETIUM TC-99M PERTECHNETATE, PER MILLICURIE"

14) Establish new code A????, "TECHNETIUM TC-99M MEBROFENIN, PER STUDY DOSE, UP TO 25 MILLICURIES"

15) Establish new code A????, "TECHNETIUM TC-99M PYROPHOSPHATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

16) Establish new code A????, "TECHNETIUM TC-99M PENETATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

17) Revise code A9516 to read "IODINE I-123 SODIUM IODIDE CAPSULE, DIAGNOSTIC AGENT, PER 100 MICROCURIES"

18) Revise code A9517 to read "IODINE I-131 SODIUM IODIDE CAPSULE, THERAPEUTIC AGENT, PER MILLICURE"

19) Establish new code A???? "TECHNETIUM TC-99M MACROAGGREGATED ALBUMIN, PER STUDY DOSE, UP TO 25 MILLICURIES"

20) Establish new code A???? "TECHNETIUM TC-99M SULFUR COLLOID, PER STUDY DOSE, UP TO 25 MILLICURIES"

21) Revise code A9521 "TECHNETIUM TC-99M EXAMETAZIME, PER STUDY DOSE, UP TO 25 MILLICURIES"

22) Establish new code A???? "INDIUM IN-111 IBRITUMOMAB TIUXETAN, DIAGNOSTIC AGENT, PER STUDY DOSE, UP TO 5 MILLICURIES"

23) Estabish new code A???? "YTTRIUM Y-90 IBRITUMOMAB TIUXETAN, THERAPUETIC AGENT, PER STUDY DOSE, UP TO 40 MILLICURIES"

24) Revise code A9524 to read: "I-131 IODINATED SERUM ALBUMIN, DIAGNOSTIC AGENT, PER 5 MICROCURIES"

25) Revise code A9526 to read "NITROGEN N-13 AMMONIA, PER STUDY DOSE, UP TO 40 MILLICURIES"

26) Revise code A9528 to read "IODINE I-131 SODIUM IODIDE CAPSULE, DIAGNOSTIC AGENT, PER MILLICURIE"

27) Revise code A9529 to read "IODINE I-131 SOUDIM IODIDE SOLUTION, DIAGNOSTIC AGENT, PER MILLICURIE"

28) Revise code A9530 to read "IODINE I-131SODIUM IODIDE SOLUTION, THERAPEUTIC AGENT, PER MILLICURIE"

29) Revise code A9531 to read "IODINE I-131 SODIUM IODIDE, DIAGNOSTIC AGENT, PER MICROCURIE (UP TO 100 MICROCURIES)

30) Revise code A9532 to read "SERUM ALBUMIN, DIAGNOSTIC AGENT, PER 5 MICROCURIES"

31) Establish new code Axxxx "IODINE I-131 TOSITUMOMAB, DIAGNOSTIC AGENT, PER STUDY DOSE, UP TO 40 MILLICURIES"

32) Establish new code Axxxx "IODINE I-131 TOSITUMOMAB, THERAPEUTIC AGENT, PER STUDY DOSE, UP TO 100 MILLICURIE"

33) Revise code A9600 to read: "STRONTIUM SR-89 CHLORIDE, PER MILLICURIE"

34) Revise code A9605 to read: "SAMARIUM SM-153 LEXIDRONAMM, 50 MILLICURIES

35) Revise code A9699 to read: "RADIOPHARMACEUTICAL THERAPEUTIC AGENT, NOT OTHERWISE CLASSIFIED"

36) Discontinue codes C1079, C1091, C1092, C1093, C1122, C1200, C1201, C1775, C9000, C9013, C9102 and C9103, eff. 12/31/2005

37) Establish new code A???? "COBALT CO-57/58, CYANOCOBALMIN, PER STUDY DOSE, UP TO 1 MICROCURIE"

38) Establish new code A???? "INDIUM IN-111 OXYQUINOLINE, PER 0.5 MILLICURIE"
39) Establish new code A???? "INDIUM IN-111 PENTETATE, PER 0.5 MILLICURIE"

40) Establish new code A???? "TECHNETIUM TC-99M ARCITUMOMAB, PER STUDY DOSE, UP TO 25 MILLICURIES"

41) Establish new code A???? "TECHNETIUM TC-99M SODIUM GLUCEPTATE, PER STUDY DOSE, UP TO 25 MILLICURIES"

42) Establish new code A???? "TECHNETIUM TC-99M SUCCIMER, PER STUDY DOSE, UP TO 25 MILLICURIES"

43) Establish new code A???? "FLUORODEOXYGLUCOSE F-18 FDG, PER STUDY DOSE, UP TO 45 MILLICURIES"

44) Establish new code A???? "CHROMIUM CR-51 SODIUM CHROMATE, PER STUDY DOSE, UP TO 0.25 MILLICURIES"

45) Establish new code A???? "IODINE I-125 SODIUM IOTHALAMATE, DIAGNOSTIC AGENT, PER 10 MICROCURIES"

46) Discontinue codes Q3000, Q3002, Q3003, Q3004, Q3005, Q3006, Q3007, Q3008, Q3009, Q3010, Q3011 and Q3012, eff. 12/31/2005

47) Establish new code A???? "RUBIDIUM RB-82, PER STUDY DOSE, UP TO 60 MILLICURIES"

48) Establish new code A???? "GALLIUM GA-67 CITRATE, PER MILLICURIE"

49) Establish new code A???? "TECHNETIUM TC-99M BICISATE, PER STUDY DOSE, UP TO 25 MILLICURES"

50) Establish new code A???? "XENON XE-133 GAS, PER 10 MILLICURIES"

51) Establish new code A???? "COBALT CO-57 CYANOCOBALAMIN, PER STUDY DOSE, UP TO 1 MICROCURIE", effective 1/1/06